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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,661	09/06/2006	Andrew Michael Lindsay Lever	6947-73323-01	3959
24197 7590 04/03/2009 KLARQUIST SPARKMAN, LLP 121 SW SALMON STREET SUITE 1600 PORTLAND, OR 97204			EXAMINER MARVICH, MARIA	
			ART UNIT	PAPER NUMBER
			1633	
			MAIL DATE	DELIVERY MODE
			04/03/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/567,661

**Applicant(s)**

LEVER ET AL.

**Examiner**

MARIA B. MARVICH

**Art Unit**

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) See Continuation Sheet are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,5,7,13-16,19,21,23,25,26,28-31,33,34,36-42,49-51 and 53-55.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,2,4,5,7,13-16,19,21,23,25,26,28-31,33,34,36-42,49-51 and 53-55.

### **DETAILED ACTION**

Claims 1,2,4,5,7,13-16,19,21,23,25,26,28-31,33,34,36-42,49-51 and 53-55 are pending in this application and subject to the following restriction.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1, 2, 4, 5, 13-16, 19, 21, 23, 25, 26, 28 and 41 are directed towards methods of producing a chimeric virus comprising the SIV capsid and a sequence with an HIV-2 packaging signal.

Group II, claims 15-29, drawn to methods of making a producer cell line comprising infecting a cell with one or more SIV nucleic acids capable of producing an SIV capsid and with a vector with HIV-2 packaging signals.

Group III, claims 33, 34 and 41, drawn to a virus produced by the method of Group I.

Group IV, claims 36-40, drawn to a first vector encoding an SIV capsid and a second vector comprising an HIV-2 packaging signal and host cells.

Group V, claims 49 and 50, drawn to a method of delivering a therapeutic or antigenic protein to an individual comprising administering a virus encoding a therapeutic or antigenic protein.

Group VI, claims 51, 53 and 54, drawn to a method of delivering a virus to a cell.

Group VII, claim 55, drawn to a method of determining the biosafety of an agent by determining the effect of a virus on a primate.

The inventions listed as Group I-VII do not relate to a single general inventive concept because they lack the same or corresponding technical feature. The unifying feature of Groups I-VII is a vector comprising sequences encoding SIV capsid and a vector comprising an HIV-2 packaging sequence, which is shown by Chang et al (see 6,207,455 which teaches use of an SIV envelope packaging line to produce chimeric vectors wherein use of an HIV-2 vector would inherently comprise a packaging signal, see col 7, line 1-14, col 12, line 12-37 and col 5, line 29-63), to lack novelty of inventive step and does not make a contribution over the prior art. Thence Groups I-VII lack a "special technical feature". Groups I, II and IV are unified by a packaging cell line comprising the vectors which is also shown by Chang to lack novelty of invention thus not making a contribution over the prior art. Groups I, III and V-VII are unified by being drawn to a virus with an SIV capsid which is demonstrated by Chang to lack novelty of invention and thus not make a contribution over the art. Furthermore, Groups IV, V and VI comprise distinct process steps and therefore do not comprise the same "special technical feature". For example, Group IV uses viruses encoding therapeutic or antigenic proteins that are delivered to individuals in order to elicit a therapeutic effect. Group V requires administration of a virus to a cell with no requirement for effect and Group VI administers virus to a primate to assess biosafety. Each method comprises steps that are not required of another and therefore, each of the methods is divergent in materials and steps. For these reasons the Inventions of Groups I- VII are patentably distinct.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable,

withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provision of MPEP 821.04. Process claims that depend for or otherwise include all the limitations of the patentable produce will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendment submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirements for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 USC 101, 101, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claim in light of *In re Ochiai*, *In re Brouwer* and 35 USC 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 USC 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Weitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD  
Examiner  
Art Unit 1633

/Maria B Marvich/  
Primary Examiner, Art Unit 1633